**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO**
**WESTERN DIVISION**

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| UNITED STATES OF AMERICA, *ex rel.* | **Civil Action No. 1:17-CV-529** |
| JEREMY W. BRIGGS,<br>JOSEPH B. LAWRENCE, and<br>MARC YOUNG | **United States District Judge**<br>**Susan J. Dlott** |
| | **FIRST AMENDED COMPLAINT** |
| BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA | |
| *Plaintiffs and Relators*, | |
| | ***Filed under seal pursuant to 31 U.S.C. § 3730(b)(2)*** |
| v. | |
| Mylan Pharmaceuticals Inc. | |
| *Defendant*. | |
| | **DO NOT SERVE** |
| | **DO NOT PUT ON PACER** |

Relators bring this action on behalf of the United States and on their own behalf and allege the following:

## I. INTRODUCTION

1. This is a *qui tam* action brought by Relators Jeremy W. Briggs, Joseph B. Lawrence, and Marc Young **("Relators**") on behalf of the United States against Defendant Mylan Pharmaceuticals Inc. to recover damages and civil penalties arising from false or fraudulent statements, records, and claims made, used, or caused to be made or used by Defendant Mylan in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*.

2. Defendant Mylan Pharmaceuticals, Inc. ("**Defendant Mylan**" or "**Mylan**") is a generic pharmaceutical manufacturer and distributor. Mylan is located in Morgantown, West Virginia.

3. Defendant Mylan falsely represented and/or certified the country of origin for pharmaceutical products as being from Trade Agreements Act ("**TAA**") designated countries in order to obtain United States Government contracts, and knowingly sold or caused the sale of non-TAA compliant pharmaceutical products to the United States in violation of the express terms of those Government Contracts. The Government Contracts at issue include Contract No. VA797P-14-C-0016 (**mirtazapine**); Contract No. VA797P-15-C-0023 (**loperamide HCL**); Contract No. VA797P-16-C-0039 (**atorvastatin CA**); Contract No. VA797P-16-C-0045 (**allopurinol**); and Contract No. VA797P-15-C-0002 (**bupropion HCL**) (collectively referred to as "**the Government Contracts**").

4. Defendant Mylan has been perpetrating this fraud scheme since at least July 15, 2014, and continuing to the present.

5. Defendant Mylan carried out this fraudulent scheme across the United States by fraudulently bidding on and accepting orders on national Government contracts for the delivery of pharmaceutical products to pharmaceutical prime vendors for distribution to various governmental participants located throughout the United States, including medical treatment facilities, formularies, and eligible Government beneficiaries.

6. Defendant Mylan's unlawful acts in violation of the False Claims Act, as alleged herein, include submitting and/or causing the submission of false claims for payment to the Federal Government for pharmaceutical products, and using materially false records and statements in support of those false claims. Defendant Mylan falsely certified and/or represented that its pharmaceutical products were from TAA-designated countries, failed to truthfully certify that its pharmaceutical products were from non-TAA designated countries, sold the Federal Government pharmaceutical products that were not TAA-compliant and were ineligible for payment, and knowingly submitted or caused to be submitted fraudulent information to the Federal Government concerning the country of origin of its pharmaceutical products for the purpose of unlawfully obtaining contracts and payments that it was not entitled to receive.

## II. PARTIES

7. Plaintiff in this action is the United States of America, on whose behalf Relators bring their claims.

8. Relator Jeremy W. Briggs is a pharmacist with more than 15 years of experience in the pharmaceutical industry. Relator Briggs has a Doctor of Pharmacy degree (PharmD) from the University of Kansas and an MBA from the University of Texas, San Antonio.

9. Relator Joseph B. Lawrence is a pharmacist with more than 20 years of experience

in the pharmaceutical industry. Relator Lawrence has a BS in Pharmacy from Southwestern Oklahoma State University, an MBA from the University of Phoenix, and a Doctor of Pharmacy degree (PharmD) from the University of Florida, College of Pharmacy.

10. Relator Marc Young is a pharmacist with extensive project management and clinical pharmaceutical expertise. Relator Young has a Doctor of Pharmacy degree (PharmD) from Idaho State University and a Master's in Pharmacy Care Systems from Auburn University.

11. Defendant Mylan is a West Virginia corporation located in Morgantown, West Virginia. Mylan is engaged in the research and development, manufacturing, and distribution of generic pharmaceutical products.

## III. JURISDICTION AND VENUE

12. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733. Relators bring this action pursuant to 31 U.S.C. § 3730(b)(1).

13. This Court has jurisdiction of the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345.

14. This Court has personal jurisdiction over Defendant Mylan because Mylan is a United States corporation conducting business in the United States and, pursuant to 31 U.S.C. § 3732(a), because Mylan transacts business and committed acts proscribed by 31 U.S.C. § 3729 within this judicial district.

15. Venue is likewise proper in this judicial district under 31 U.S.C. § 3732(a) because Defendant Mylan transacts business and committed acts proscribed by 31 U.S.C. § 3729 in this judicial district and in this division.

16. Personal jurisdiction and venue are proper in this district (and for venue in this

division) specifically because, in violation of the express terms of its Government Contracts, Defendant Mylan caused the distribution of and sought reimbursement for non-TAA compliant pharmaceutical products distributed to the following Government entities located within this district and this division: the VA Medical Center located at 3200 Vine Street Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505. Defendant Mylan also transacted business and committed acts proscribed by 31 U.S.C. § 3729 in this district: 1) by submitting claims for payment to the United States and receiving payment from the United States through Government pharmaceutical prime vendor Cardinal Health, Inc., ("**Cardinal Health**") which is located in this district in Dublin, Ohio; and 2) by distributing drugs pursuant to its Government Contracts through Government pharmaceutical prime vendors including Amerisource Bergen Drug Co. which maintains a distribution center in this district in Lockbourne, Ohio.

## IV. THE FALSE CLAIMS ACT

17. The False Claims Act ("**FCA**") imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. . ." 31 U.S.C. § 3729(a)(1)(A).

18. The FCA also imposes liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. . ." 31 U.S.C. § 3729(a)(1)(B).

19. The FCA defines "knowingly" to "mean that a person, with respect to

information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

20. Under the FCA, the term "claim"

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government —
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
>
> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

31 U.S.C. § 3729(b)(2).

21. Prior to filing this FCA action, Relators served upon the United States a copy of this complaint and a written disclosure of substantially all material evidence and information they possessed, in accord with 31 U.S.C. § 3730(b)(2). Prior to filing their First Amended Complaint, Relators served upon the United States a copy of their First Amended Complaint and a supplemental written disclosure.

22. There has been no prior "public[] disclos[ure]," as that term is used in 31 U.S.C. § 3730(e)(4)(A), of the allegations and transactions on which this FCA action is based.

23. Relators are "original source[s]" of the information upon which the allegations and transactions in their originally filed complaint and in this First Amended Complaint are based, in accord with 31 U.S.C. § 3730(e)(4)(B).

## V. DEFENDANT MYLAN'S GOVERNMENT CONTRACTS REQUIRE COMPLIANCE WITH THE TRADE AGREEMENTS ACT

24. Pursuant to its Government Contracts, Defendant Mylan is required to provide pharmaceutical products that are end products of a Trade Agreements Act designated country.

25. In violation of the express terms of Mylan's Government Contracts, Defendant Mylan knowingly sold or caused the sale of pharmaceutical products from non-TAA designated countries to the United States.

### A. Trade Agreements Act Requirements

26. The Trade Agreements Act ("**TAA**"), 19 U.S.C. § 2501, *et seq*., requires that certain products procured by the United States Government must have specific designated countries as their country of origin.[1]

27. The TAA was enacted, in part, "to foster the growth and maintenance of an open world trading system" and "to expand opportunities for the commerce of the United States in international trade . . . ."[2]

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[1] *See* 19 U.S.C. § 2512(a)(1)(A) (the President shall prohibit the procurement of products from non-designated foreign countries); *see also* 48 C.F.R. § 25.403(c)(1) (Under the TAA, the United States is to acquire only U.S.-made or designated country end products, for acquisitions covered by the World Trade Organization Government Procurement Agreement); 48 C.F.R. § 225.403(c) (same).

[2] 19 U.S.C. § 2502.

28. The TAA applies to Government procurement contracts that equal or exceed certain threshold amounts. *See, e.g.*, 48 C.F.R. § 25.1101(c)(1); 48 C.F.R. § 225.1101(6); 78 Fed. Reg. 76700 (Dec. 18, 2013).[3]

29. Only specified countries qualify as TAA-designated countries of origin for products acquired by the United States Government.[4]

30. India, China, Brazil, and Russia are among the non-permitted countries of origin under the TAA.[5]

31. For an end product that consists of materials from more than one country, that end product's country of origin is the place where the materials have been "substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed." 19 U.S.C. § 2518(4)(B); 19 C.F.R. § 177.22(a).

32. The country of origin for a pharmaceutical product is the country in which the drugs's active pharmaceutical ingredient ("**API**") was sourced or produced.

33. Defendant Mylan knows, as that term is defined in the FCA, that the country of origin for the following pharmaceutical products it sold to the Government (pursuant to contracts requiring TAA-compliant end products) were not TAA-designated countries:

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[3] For example, for calendar years 2012 and 2013, the TAA threshold amount for applicability was $202,000.00. 76 Fed. Reg. 76808, 76809 (Dec. 8, 2011). For calendar years 2014 and 2015, the TAA threshold amount for applicability was $204,000.00. 78 Fed. Reg. 76700 (Dec. 18, 2013). For calendar years 2016 and 2017, the TAA threshold amount for applicability was $191,000.00. 80 Fed. Reg. 77,694, 77695 (Dec. 15, 2015).

[4] *See* 48 C.F.R. § 52.225-5; 48 C.F.R. § 252.225-7021.

[5] *See, e.g.*, 48 C.F.R. § 52.225-5.

a. mirtazapine;

b. loperamide HCL;

c. atorvastatin CA;

d. allopurinol; and

e. buproprion HCL.

34. As described more fully below, Defendant Mylan is knowingly selling non-TAA compliant pharmaceutical products to the United States in violation of the False Claims Act.

**B. The Pharmaceutical Prime Vendor Program**

35. The Pharmaceutical Prime Vendor Program ("**PPV Program**") is the contracting method used by the United States Government to distribute drugs and other pharmaceutical products to the nation's veterans and to certain other Federal Government agencies.

36. Through the PPV Program, the Department of Veterans Affairs ("**VA**") provides pharmaceutical products to various VA facilities, to the Indian Health Service ("**IHS**"), to the Bureau of Prisons ("**BoP**"), and to other governmental entities. Authorized State Veterans Homes that have sharing agreements with VA facilities are also eligible participants in the PPV Program.

37. The Defense Logistics Agency ("**DLA**") likewise provides pharmaceutical products to the Department of Defense ("**DoD**") and to other governmental entities through the PPV Program.

38. Under the PPV Program, pharmaceutical distributors, including Defendant Mylan, enter into contracts with the VA and the DLA. These Government contracts establish a national contract price for specific pharmaceutical products to be distributed through the PPV Program.

39. Pursuant to these VA and DLA contracts, the contractor agrees to allow the designated VA and DLA/DoD Pharmaceutical Prime Vendors to deliver the specified pharmaceutical products to various governmental entities.

40. A Pharmaceutical Prime Vendor ("**PPV**") is an independent business entity that functions as the primary distributor of specified classes of products such as drugs and pharmaceuticals for purchasers like VA hospitals and DoD medical facilities.

41. Contractors, including Defendant Mylan, are required to provide the pharmaceutical products specified at the prices established in the contract to designated PPVs for distribution to DoD, VA, BoP, IHS, and to other governmental entities.

42. The PPVs place orders with the contractor for delivery to the PPVs for distribution to these various governmental participants.

43. Under the terms of a Government contract with the VA or DLA, pharmaceutical providers, including Defendant Mylan, agree to accept orders from PPVs and provide pharmaceutical products to the PPVs at the prices agreed to in the Government contract for use by the medical treatment facilities, formularies, and eligible beneficiaries served by those PPVs.

44. Pharmaceutical providers, including Defendant Mylan, are required to report the dollar value of all sales made under a VA or DLA contract by calendar quarter. These reported sales must include all sales made, whether shipped directly to the users or through PPVs.

45. Under the terms of a VA or DLA contract, pharmaceutical providers, including Defendant Mylan, are paid for the pharmaceutical products they deliver to PPVs by those PPVs using Government funds.

46. Defendant Mylan knowingly sold non-TAA compliant pharmaceutical products to the United States through the PPV program in violation of the False Claims Act.

47. TAA compliance is material to the Government. The Government regularly rejects bids for national contracts to supply pharmaceutical products when the TAA-compliance provision is not satisfied.

## VI. MYLAN IS KNOWINGLY VIOLATING ITS GOVERNMENT CONTRACTS BY SUPPLYING NON-TAA COMPLIANT PHARMACEUTICAL PRODUCTS

48. As is described below in detail, the Government Contracts at issue in this Complaint required Mylan to supply the Government with TAA-compliant pharmaceutical products.

49. Defendant Mylan falsely certified its compliance with the Trade Agreements requirements of its Government Contracts.

50. Because Mylan knowingly failed to supply TAA-compliant pharmaceutical products and because Mylan falsely certified and/or represented its compliance with the Trade Agreements provisions in its Government Contracts, all claims for payment under the contracts identified below are false claims.

### A. The Mirtazapine Contract: VA Contract No. VA797P-14-C-0016

51. On June 25, 2014, the VA issued Solicitation No. VA797P-14-R-0015 seeking offers to supply its requirements of mirtazapine tablets.

52. Mirtazapine is a generic version of the brand name drug Remeron. It is used to treat major depressive disorder.

53. By making an offer on Solicitation No. VA797P-14-R-0015, Defendant Mylan

agreed to furnish and deliver mirtazapine tablets subject to the terms and conditions specified in the solicitation.

54. On July 15, 2014, Defendant Mylan was awarded Contract No. VA797P-14-C-0016 to supply mirtazapine tablets to the VA pursuant to Solicitation No. VA797P-14-R-0015 (collectively the "**Mirtazapine Contract**").

55. The Mirtazapine Contract is a firm fixed price requirements contract whereby Defendant Mylan agreed to supply mirtazapine tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

56. The Mirtazapine Contract is for one base year, with four one-year option years.

57. The Mirtazapine Contract has a contract award amount of $4,188,874.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

58. The effective date of the base year of the Mirtazapine Contract was August 28, 2014.

59. On August 11, 2015, the VA exercised the first one year option available under the Mirtazapine Contract, permitting governmental entities to place orders under that contract from August 28, 2015 through August 27, 2016.

60. On July 21, 2016, the VA exercised the second option year available under the Mirtazapine Contract, permitting governmental entities to place orders under that contract from August 28, 2016 through August 27, 2017.

61. On July 20, 2017, the VA exercised the third option year available under the Mirtazapine Contract, permitting governmental entities to place orders under that contract from August 28, 2017 through August 27, 2018.

62. The products awarded under the Mirtazapine Contract are ordered and distributed through the PPV Program.

63. The Mirtazapine Contract specifies that PPVs will accept Government orders of mirtazapine and payment for such orders on behalf of Defendant Mylan.

64. The Mirtazapine Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

65. The governmental facilities served under the Mirtazapine Contract include the VA Medical Center located at 3200 Vine Street Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

66. The Mirtazapine Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and are the lowest price technically acceptable."

67. The Mirtazapine Contract also provides that the Government may terminate the contract for cause if Defendant Mylan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Mylan shall be liable to the Government for any and all rights and remedies provided by law.

68. The Mirtazapine Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

69. The Mirtazapine Contract specifically requires Defendant Mylan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. § 3301 note).

70. The Mirtazapine Contract also specifically requires Defendant Mylan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Mirtazapine Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[6]

71. Mylan is required to certify Trade Agreements compliance on an annual basis.

72. By submission of its offer for the Mirtazapine Contract and in its annual certifications, Mylan verified that its Trade Agreements certification was accurate, complete, applicable to this solicitation, and incorporated by reference.

73. However, contrary to Mylan's representations, the mirtazapine tablets Defendant Mylan provides to governmental entities under Contract No. VA797P-14-C-0016 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

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[6] No such determinations were made by the Contracting Officer.

74. The mirtazapine tablets supplied by Defendant Mylan under the Mirtazapine Contract are end products of a non-TAA designated country of origin.

75. In order to obtain the Mirtazapine Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Mylan falsely certified that the mirtazapine it was selling to the Government was a "U.S.-made or designated country end product."

76. Because the mirtazapine tablets distributed by Defendant Mylan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-14-C-0016.

77. Defendant Mylan falsely represented that the mirtazapine it supplied under Contract No. VA797P-14-C-0016 was a TAA-compliant product.

78. Defendant Mylan's certifications that the mirtazapine tablets supplied under Contract No. VA797P-14-C-0016 were made in the United States or in a TAA "designated country" were false. Mylan made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

79. As specified in the Mirtazapine Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Mirtazapine Contract, or option years under that contract, to Mylan and Mylan would not have been paid any money for mirtazapine tablets if Mylan had truthfully disclosed in its bid that the country of origin for the mirtazapine tablets was a non-TAA country of origin.

80. All claims for payment for mirtazapine tablets supplied by Defendant Mylan under Contract No. VA797P-14-C-0016 are false claims.

**B. The Loperamide HCL Contract: VA Contract No. VA797P-15-C-0023**

81. On January 16, 2015, the VA issued Solicitation No. VA797P-15-R-0046 seeking offers to supply its requirements of loperamide HCL capsules.

82. Loperamide HCL is a generic version of the brand name drug Imodium A-D. It is used to treat diarrhea.

83. By making an offer on Solicitation No. VA797P-15-R-0046, Defendant Mylan agreed to furnish and deliver loperamide HCL capsules subject to the terms and conditions specified in the solicitation.

84. On April 30, 2015, Defendant Mylan was awarded Contract No. VA797P-15-C-0023 to supply loperamide HCL capsules to the VA pursuant to Solicitation No. VA797P-15-R-0046 (collectively the "**Loperamide HCL Contract**").

85. The Loperamide HCL Contract is a firm fixed price requirements contract whereby Defendant Mylan agreed to supply loperamide HCL capsules for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

86. The Loperamide HCL Contract is for one base year, with four one-year option years.

87. The Loperamide HCL Contract has a contract award amount of $6,625,235.45. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

88. The effective date of the base year of the Loperamide HCL Contract was July 30, 2015.

89. On July 8, 2016, the VA exercised the first one year option available under the Loperamide HCL Contract, permitting governmental entities to place orders under that contract from July 30, 2016 through July 29, 2017.

90. On July 14, 2017, the VA exercised the second one year option available under the Loperamide HCL Contract, permitting governmental entities to place orders under that contract from July 30, 2017 through July 29, 2018.

91. The products awarded under the Loperamide HCL Contract are ordered and distributed through the PPV Program.

92. The Loperamide HCL Contract specifies that PPVs will accept Government orders of loperamide HCL and payment for such orders on behalf of Defendant Mylan.

93. The Loperamide HCL Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

94. The governmental facilities served under the Loperamide HCL Contract include the VA Medical Center located at 3200 Vine Street Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

95. The Loperamide HCL Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

96. The Loperamide HCL Contract also provides that the Government may terminate the contract for cause if Defendant Mylan fails to comply with any contract terms and conditions.

In the event of such a termination for cause, Defendant Mylan shall be liable to the Government for any and all rights and remedies provided by law.

97. The Loperamide HCL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

98. The Loperamide HCL Contract specifically requires Defendant Mylan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. § 3301 note).

99. The Loperamide HCL Contract also specifically requires Defendant Mylan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Loperamide HCL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[7]

100. Mylan is required to certify Trade Agreements compliance on an annual basis.

101. By submission of its offer for the Loperamide HCL Contract and in its annual certifications, Mylan verified that its Trade Agreements certification was accurate, complete, and applicable to this solicitation, and incorporated by reference.

102. However, contrary to Mylan's representations, the loperamide HCL capsules Defendant Mylan provides to governmental entities under Contract No. VA797P-15-C-0023 are

[7] No such determinations were made by the Contracting Officer.

not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

103. The loperamide HCL capsules supplied by Defendant Mylan under the Loperamide HCL Contract are end products of a non-TAA designated country of origin.

104. In order to obtain the Loperamide HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Mylan falsely certified that the loperamide HCL it was selling to the Government was a "U.S.-made or designated country end product."

105. Because the loperamide HCL capsules distributed by Defendant Mylan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0023.

106. Defendant Mylan falsely represented that the loperamide HCL it supplied under Contract No.VA797P-15-C-0023 was a TAA-compliant product.

107. Defendant Mylan's certifications that the loperamide HCL capsules supplied under Contract No. VA797P-15-C-0023 were made in the United States or in a TAA "designated country" were false. Mylan made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

108. As specified in the Loperamide HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Loperamide HCL Contract, or option years under that contract, to Mylan and Mylan would not have been paid any money for loperamide HCL capsules if Mylan had truthfully disclosed in its bid that the country of origin for the loperamide HCL capsules was a non-TAA country of origin.

109. All claims for payment for loperamide HCL capsules supplied by Defendant Mylan under Contract No. VA797P-15-C-0023 are false claims.

**C. The Atorvastatin CA Contract: VA Contract No. VA797P-16-C-0039**

110. On December 16, 2015, the VA issued Solicitation No. VA797P-16-R-0016 seeking offers to supply its requirements of atorvastatin CA tablets.

111. Atorvastatin CA is a generic version of the brand name drug Lipitor. It is used to treat patients with high levels of cholesterol.

112. By making an offer on Solicitation No. VA797P-16-R-0016, Defendant Mylan agreed to furnish and deliver atorvastatin CA tablets subject to the terms and conditions specified in the solicitation.

113. On March 29, 2016, Defendant Mylan was awarded Contract No. VA797P-16-C-0039 to supply atorvastatin CA tablets to the VA pursuant to Solicitation No. VA797P-16-R-0016 (collectively the "**Atorvastatin CA Contract**").

114. The Atorvastatin CA Contract is a firm fixed price requirements contract whereby Defendant Mylan agreed to supply atorvastatin CA tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

115. The Atorvastatin CA Contract is for one base year, with four one-year option years.

116. The Atorvastatin CA Contract has a contract award amount of $91,037,468.80. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

117. The effective date of the base year of the Atorvastatin CA Contract was May 24, 2016.

118. On April 25, 2017, the VA exercised the first one year option available under the Atorvastatin CA Contract, permitting governmental entities to place orders under that contract from May 24, 2017 through May 23, 2018.

119. The products awarded under the Atorvastatin CA Contract are ordered and distributed through the PPV Program.

120. The Atorvastatin CA Contract specifies that PPVs will accept Government orders of atorvastatin CA and payment for such orders on behalf of Defendant Mylan.

121. The Atorvastatin CA Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

122. The governmental facilities served under the Atorvastatin CA Contract include the VA Medical Center located at 3200 Vine Street Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

123. The Atorvastatin CA Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

124. The Atorvastatin CA Contract also provides that the Government may terminate the contract for cause if Defendant Mylan fails to comply with any contract terms and conditions.

In the event of such a termination for cause, Defendant Mylan shall be liable to the Government for any and all rights and remedies provided by law.

125. The Atorvastatin CA Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

126. The Atorvastatin CA Contract specifically requires Defendant Mylan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. § 3301 note).

127. The Atorvastatin CA Contract also specifically requires Defendant Mylan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Atorvastatin CA Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[8]

128. Mylan is required to certify Trade Agreements compliance on an annual basis.

129. By submission of its offer for the Atorvastatin CA Contract and in its annual certifications, Mylan verified that its Trade Agreements certification was accurate, complete, applicable to this solicitation, and incorporated by reference.

130. However, contrary to Mylan's representations, the atorvastatin CA tablets Defendant Mylan provides to governmental entities under Contract No. VA797P-16-C-0039 are

[8] No such determinations were made by the Contracting Officer.

not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

131. The atorvastatin CA tablets supplied by Defendant Mylan under the Atorvastatin CA Contract are end products of a non-TAA designated country of origin.

132. In order to obtain the Atorvastatin CA Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Mylan falsely certified that the atorvastatin CA it was selling to the Government was a "U.S.-made or designated country end product."

133. Because the atorvastatin CA tablets distributed by Defendant Mylan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0039.

134. Defendant Mylan falsely represented that the atorvastatin CA it supplied under Contract No. VA797P-16-C-0039 was a TAA-compliant product.

135. Defendant Mylan's certifications that the atorvastatin CA tablets supplied under Contract No. VA797P-16-C-0039 were made in the United States or in a TAA "designated country" were false. Mylan made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

136. As specified in the Atorvastatin CA Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Atorvastatin CA Contract, or option years under that contract, to Mylan and Mylan would not have been paid any money for atorvastatin CA tablets if Mylan had truthfully disclosed in its bid that the country of origin for the atorvastatin CA tablets was a non-TAA country of origin.

137. All claims for payment for atorvastatin CA tablets supplied by Defendant Mylan under Contract No. VA797P-16-C-0039 are false claims.

**D. The Allopurinol Contract: VA Contract No. VA797P-16-C-0045**

138. On January 22, 2016, the VA issued Solicitation No. VA797P-16-R-0032 seeking offers to supply its requirements of allopurinol tablets.

139. Allopurinol is a generic version of the brand name drug Zyloprim. It is used to treat gout and kidney stones and to reduce uric acid levels.

140. By making an offer on Solicitation No. VA797P-16-R-0032, Defendant Mylan agreed to furnish and deliver allopurinol tablets subject to the terms and conditions specified in the solicitation.

141. On March 30, 2016, Defendant Mylan was awarded Contract No. VA797P-16-C-0045 to supply allopurinol tablets to the VA pursuant to Solicitation No. VA797P-16-R-0032 (collectively the "**Allopurinol Contract**").

142. The Allopurinol Contract is a firm fixed price requirements contract whereby Defendant Mylan agreed to supply allopurinol tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

143. The Allopurinol Contract is for one base year, with four one-year option years.

144. The Allopurinol Contract has a contract award amount of $39,850,987.50. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

145. The effective date of the base year of the Allopurinol Contract was May 30, 2016.

146. On May 22, 2017, the VA exercised the first one year option available under the

Allopurinol Contract, permitting governmental entities to place orders under that contract from May 30, 2017 through May 29, 2018.

147. The products awarded under the Allopurinol Contract are ordered and distributed through the PPV Program.

148. The Allopurinol Contract specifies that PPVs will accept Government orders of allopurinol and payment for such orders on behalf of Defendant Mylan.

149. The Allopurinol Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

150. The governmental facilities served under the Allopurinol Contract include the VA Medical Center located at 3200 Vine Street Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

151. The Allopurinol Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

152. The Allopurinol Contract also provides that the Government may terminate the contract for cause if Defendant Mylan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Mylan shall be liable to the Government for any and all rights and remedies provided by law.

153. The Allopurinol Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

154. The Allopurinol Contract specifically requires Defendant Mylan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. § 3301 note).

155. The Allopurinol Contract also specifically requires Defendant Mylan to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Allopurinol Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[9]

156. Mylan is required to certify Trade Agreements compliance on an annual basis.

157. By submission of its offer for the Allopurinol Contract and in its annual certifications, Mylan verified that its Trade Agreements certification was accurate, complete, applicable to this solicitation, and incorporated by reference.

158. However, contrary to Mylan's representations, the allopurinol tablets Defendant Mylan provides to governmental entities under Contract No. VA797P-16-C-0045 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

159. The allopurinol tablets supplied by Defendant Mylan under the Allopurinol Contract are end products of a non-TAA designated country of origin.

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[9] No such determinations were made by the Contracting Officer.

160. In order to obtain the Allopurinol Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Mylan falsely certified that the allopurinol it was selling to the Government was a "U.S.-made or designated country end product."

161. Because the allopurinol tablets distributed by Defendant Mylan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0045.

162. Defendant Mylan falsely represented that the allopurinol it supplied under Contract No. VA797P-16-C-0045 was a TAA-compliant product.

163. Defendant Mylan's certifications that the allopurinol tablets supplied under Contract No. VA797P-16-C-0045 were made in the United States or in a TAA "designated country" were false. Mylan made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

164. As specified in the Allopurinol Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Allopurinol Contract, or option years under that contract, to Mylan and Mylan would not have been paid any money for allopurinol tablets if Mylan had truthfully disclosed in its bid that the country of origin for the allopurinol tablets was a non-TAA country of origin.

165. All claims for payment for allopurinol tablets supplied by Defendant Mylan under Contract No. VA797P-16-C-0045 are false claims.

### E. The Bupropion HCL Contract: VA Contract No. VA797P-15-C-0002

166. On September 12, 2014, the VA issued Solicitation No. VA797P-14-R-0060 seeking offers to supply its requirements of bupropion HCL tablets.

167. Bupropion HCL is a generic version of the brand name drugs Wellbutrin XL and Zyban. It is an antidepressant medication that is used to treat major depressive disorder and seasonal affective disorder.

168. By making an offer on Solicitation No. VA797P-14-R-0060, Defendant Mylan agreed to furnish and deliver bupropion HCL tablets subject to the terms and conditions specified in the solicitation.

169. On October 17, 2014, Defendant Mylan was awarded Contract No. VA797P-15-C-0002 to supply bupropion HCL tablets to the VA pursuant to Solicitation No. VA797P-14-R-0060 (collectively the "**Bupropion HCL Contract**").

170. The Bupropion HCL Contract is a firm fixed price requirements contract whereby Defendant Mylan agreed to supply bupropion HCL tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

171. The Bupropion HCL Contract is for one base year, with four one-year option years.

172. The Bupropion HCL Contract has a contract award amount of $9,433,334.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

173. The effective date of the base year of the Bupropion HCL Contract was November 14, 2014.

174. On or about October 28, 2015, the VA exercised the first one year option available under the Bupropion HCL Contract, permitting governmental entities to place orders under that contract from November 14, 2015 through November 13, 2016.

175. On November 1, 2016, the VA exercised the second one year option available under the Bupropion HCL Contract, permitting governmental entities to place orders under that contract from November 14, 2016 through November 13, 2017.

176. On November 9, 2017, the VA exercised the third one year option available under the Bupropion HCL Contract, permitting governmental entities to place orders under that contract from November 14, 2017 through November 13, 2018.

177. The products awarded under the Bupropion HCL Contract are ordered and distributed through the PPV Program.

178. The Bupropion HCL Contract specifies that PPVs will accept Government orders of bupropion HCL and payment for such orders on behalf of Defendant Mylan.

179. The Bupropion HCL Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

180. The Bupropion HCL Contract states that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

181. The Bupropion HCL Contract provides that the Government may terminate the contract for cause if Defendant Mylan fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant Mylan shall be liable to the Government for any and all rights and remedies provided by law.

182. The Bupropion HCL Contract also provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

183. The Bupropion HCL Contract specifically requires Defendant Mylan to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. § 3301 note).

184. The Bupropion HCL Contract also specifically requires Defendant Mylan to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Bupropion HCL Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[10]

185. Mylan is required to certify Trade Agreements compliance on an annual basis.

186. By submission of its offer for the Bupropion HCL Contract and in its annual certifications, Mylan verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

187. However, contrary to Mylan's representations, the bupropion HCL tablets Mylan provides to governmental entities under Contract No. VA797P-15-C-0002 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

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[10] No such determinations were made by the Contracting Officer.

188. The bupropion HCL tablets supplied by Defendant Mylan under the Bupropion HCL Contract are end products of a non-TAA designated country of origin.

189. In order to obtain the Bupropion HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant Mylan falsely certified that the bupropion HCL it was selling to the Government was a "U.S.-made, designated country end product."

190. Because the bupropion HCL tablets distributed by Defendant Mylan are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0002.

191. Defendant Mylan's certifications that the bupropion HCL tablets supplied under Contract No. VA797P-15-C-0002 were made in the United States or in a TAA "designated country" were false. Mylan made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

192. As specified in the Bupropion HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Bupropion HCL Contract, or option years under that contract, to Defendant Mylan and Mylan would not have been paid any money for bupropion HCL tablets if Mylan had truthfully disclosed in its bid that the country of origin for the bupropion HCL tablets was a non-TAA country of origin.

193. All claims for payment for bupropion HCL tablets supplied by Defendants under Contract No. VA797P-15-C-0002 are false claims.

**COUNT I-VIOLATION OF 31 U.S.C. § 3729(A)(1)(A)**

194. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

195. Defendant Mylan, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

196. By virtue of the conduct described above, Defendant Mylan knowingly presented or caused to be presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(A).

197. Defendant Mylan "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant Mylan acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

198. As a result of Defendant Mylan's violations of 31 U.S.C. § 3729(a)(1)(A), the Government has suffered actual damages in an amount to be determined at trial.

**COUNT II-VIOLATION OF 31 U.S.C. § 3729(A)(1)(B)**

199. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

200. Defendant Mylan, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

201. By virtue of the conduct described above, Defendant Mylan knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

202. Defendant Mylan "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant Mylan acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

203. As a result of Defendant Mylan's violations of 31 U.S.C. § 3729(a)(1)(B), the Government has suffered actual damages in an amount to be determined at trial.

**PRAYER FOR RELIEF**

WHEREFORE Relators, on behalf of themselves and the United States, pray for judgment against Defendant Mylan as follows:

A. That this Court enter judgment against Defendant Mylan in an amount equal to three times the amount of damages sustained by the United States because of Defendant Mylan's acts in violation of the False Claims Act, plus the maximum civil penalty for each violation of the False Claims Act, as provided by 31 U.S.C. § 3729(a)(1);

B. That Relators be awarded all reasonable expenses incurred, plus reasonable attorneys' fees and costs, in accord with 31 U.S.C. § 3730(d);

C. That, in the event the United States intervenes, that Relators be awarded 25% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(1);

D. That, in the event the United States does not intervene, that Relators be awarded 30% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(2);

E. That Relators be awarded a share of any alternate remedy that the United States elects to pursue;

F. That Defendant Mylan, its subsidiaries, affiliates, and related organizations be found to have violated the False Claims Act and be enjoined from future violations of that act;

G. That the United States and Relators be awarded pre-judgment and post-judgment interest; and

H. That the United States and Relators receive all relief, both at law and in equity to which they may be reasonably entitled.

Respectfully submitted,

Date: January 10, 2018

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 10, 2018, I served the foregoing:

*Via Federal Express and Certified U.S. Mail upon*:
Hon. Jefferson B. Sessions
Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue N.W.
Washington, D.C. 20530

*And Via Hand Delivery upon:*
Hon. Benjamin C. Glassman
United States Attorney
Hon. William B. King II
Assistant United States Attorney
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202

Julie W. Popham

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